AT

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,480	11/07/2001	Pia M. Challita-Eid	511582006200	7228

36327 7590 05/24/2004

AGENSYS C/O MORRISON & FOERSTER LLP
3811 VALLEY CENTRE DRIVE, SUITE 500
SAN DIEGO, CA 92130

EXAMINER	
BLANCHARD, DAVID J	
ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 05/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/005,480	CHALLITA-EID ET AL.	
	Examiner	Art Unit	
	David J Blanchard	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4-7,9-15,65-70 and 75-89* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *4-7,9-15,65-70 and 75-89* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10, 12-13 and 78-83, drawn an antibody that binds to a protein at least 90% homologous to SEQ ID NOS:743 or 745, classified in class 530, subclass 387.9.

II. Claim 11, drawn to a non-human transgenic animal that produces an antibody that specifically binds to a to a protein at least 90% homologous to SEQ ID NOS:743 or 745, classified in class 800, subclass 6.

III. Claim 14, drawn to DNA encoding a single-chain antibody that binds a protein at least 90% homologous to SEQ ID NOS:743 or 745, classified in class 535, subclass 23.53.

IV. Claims 15 and 84-89, drawn to a method of delivering an agent that is conjugated to an antibody that binds to a protein at least 90% homologous to SEQ ID NOS:743 or 745, classified in class 424, subclass 139.1.

V. Claims 65-66 in part and claim 67, drawn to a method of inducing a B cell that generates antibodies that bind to a protein at least 90% homologous to SEQ ID NOS:743 or 745 using an immunogenic portion of said protein, classified in class 435, subclass 69.6. If Group IV is elected, the claims will be examined to the extent that the protein comprises at least one B cell epitope.

VI. Claims 65-66 in part and claim 67, drawn to a method of inducing a B cell that generates antibodies that bind to a protein at least 90% homologous to SEQ ID NOS:743 or 745 using a nucleic acid that encodes said protein, classified in class 435, subclass 69.6. If Group V is elected, the claims will be examined to the extent that the nucleic acid that encodes the protein comprises at least one B cell epitope.

VII. Claims 65-66 in part and claims 68-69, drawn to a method of activating a cytotoxic T cell that kills an autologous cell expressing a protein having at least 90% homologous to SEQ ID NOS:743 or 745 using an immunogenic portion of said protein, classified in class 424, subclass 185.1. If Group VI is elected, the claims will be examined to the extent that the protein comprises at least one T cell epitope.

VIII. Claims 65-66 in part and claims 68-69, drawn to a method of activating a cytotoxic T cell that kills an autologous cell expressing a protein having at least 90% homologous to SEQ ID NOS:743 or 745 using a nucleic acid that encodes said protein, classified in class 424, subclass 185.1. If Group VII is elected, the claims will be examined to the extent that the nucleic acid that encodes the protein comprises at least one T cell epitope,

IX. Claim 70 drawn to an assay for detecting the presence of a protein having at least 90% homology to SEQ ID NOS:743 or 745 with an antibody that

binds to a protein at least 90% homologous to SEQ ID NOS:743 or 745, classified in class 435, subclass 7.1.

X. Claims 75-76 in part and claim 77, drawn to a method of detecting expression levels of 161P2F10B mRNA, classified in class 435, subclass 6.

XI. Claims 75-76 in part and claim 77, drawn to a method of detecting expression levels of 161P2F10B protein, classified in class 435, subclass 7.92.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I-III represent separate and distinct products, which are made by materially different methods, and are used in materially different methods, which have different modes of operation, different functions and different effects. The antibody of Group I, the transgenic animal of Group II and the polynucleic acid of Group II are structurally and chemically different from each other. The polynucleotide is made by nucleic acid synthesis, while the antibody is raised by immunization. Furthermore, the polynucleotide can be used for hybridization screening, the antibody can be used to purify the antigen, for example. The examination of all groups would require different searches in the U.S. Patent shoes and the scientific literature and would require the consideration of different patentability issues. Thus the inventions I-IIIare patentably distinct.

The methods of Inventions IV-XI differ in the method objectives, method steps and parameters and in the reagents used. Invention IV recites a method of delivering an agent that is conjugated to an antibody that binds to a protein at least 90% homologous to SEQ ID NOS:743 or 745; Invention V recites a method of inducing a B cell that generates antibodies that bind to a protein at least 90% homologous to SEQ ID NOS:743 or 745 using an immunogenic portion of said protein; Invention VI recites a method of inducing a B cell that generates antibodies that bind to a protein at least 90% homologous to SEQ ID NOS:743 or 745 using a nucleic acid that encodes said protein; Invention VII recites a method of activating a cytotoxic T cell that kills an autologous cell expressing a protein having at least 90% homologous to SEQ ID NOS:743 or 745 using an immunogenic portion of said protein; Invention VIII recites a method of activating a cytotoxic T cell that kills an autologous cell expressing a protein having at least 90% homologous to SEQ ID NOS:743 or 745 using a nucleic acid that encodes said protein; Invention IX recites an assay for detecting the presence of a protein having at least 90% homology to SEQ ID NOS:743 or 745; Invention X recites a method of detecting expression levels of 161P2F10B mRNA; Invention XI recites a method of detecting expression levels of 161P2F10B protein. The examination of all groups would require different searches in the U.S. Patent shoes and the scientific literature and would require the consideration of different patentability issues. Thus, inventions IV-XI are separate and distinct in having different method objectives, method steps and different endpoints and are patentably distinct.

Inventions I and (IV and VII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Group I can be used in a materially different method such as to purify the antigen in addition to the materially different methods of Groups IV and VII.

Inventions (V and VI) and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the antibody of Group I can be made by tapping the repertoire of rearranged V-genes from the peripheral blood lymphocytes of unimmunised donors in addition to the materially different methods of Groups V and VI, which differ in the method steps and reagents used.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise

include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at (571) 272-0827 from 8:00 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (571) 272-0841.

Official papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The official fax number for Group 1600 where this application or proceeding is assigned is (703) 872-9306.

Respectfully,
David J. Blanchard
571-272-0827

LARRY R. HELMS, PH.D
PRIMARY EXAMINER